



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/580,999

03/12/2007

Julia Y. Ljubimova

67789-118US0

9455

50670

7590

12/07/2010

DAVIS WRIGHT TREMAINE LLP/Los Angeles  
865 FIGUEROA STREET  
SUITE 2400  
LOS ANGELES, CA 90017-2566

EXAMINER

EPSS -SMITH, JANET L

ART UNIT

PAPER NUMBER

1633

NOTIFICATION DATE

DELIVERY MODE

12/07/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentlax@dwt.com  
sethlevy@dwt.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/580,999	<b>Applicant(s)</b> LJUBIMOVA ET AL.	
	<b>Examiner</b> Janet L. Epps-Smith	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 18-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/9/10, 6/9/10</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. Claims 1-13 and 18-23 are pending and are under examination.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Priority***

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) to provisional application 60/527,300 is acknowledged. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).
4. The disclosure of the prior-filed application, Application No. 60/527,300, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The disclosure of the provisional application is specifically limited to "a multifunctional drug delivery system consisting of a molecular construct comprising molecular modules attached to the pending carboxyl groups of a polymalic acid backbone." Instant claim 1 is broadly drawn to any polymerized carboxylic acid molecular scaffold, comprising a plurality of "free carboxylic acid groups," wherein the scaffold is a homopolymers. The provisional is specifically limited to delivery systems that involve polymalic acid, wherein the

Art Unit: 1633

molecular modules are attached to the pending carboxyl groups. The instant claims do not require direct attachment to the pending carboxyl groups. Thus the instant claims are broader than the disclosure of the provisional application. Therefore, the instant claims are not granted the filing date of the provisional application.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-2, 6-13, and 18-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter).

7. Applicants have amended the instant claims to recite the limitation "wherein the scaffold is a homopolymer." With the exception of homopolymers of polymalic acid, the specification as filed does not provide support for any other form of homopolymeric scaffolds comprising a plurality of free carboxylic acid groups according to the present invention.

8. As support for this amendment, Applicants referred to paragraphs 58, 86, 90 and Figure 1 of the specification. However, each reference to the specification is a reference to polymalic acid. Applicant's amendment is therefore considered new matter since the scope of claims does not find support in the specification as originally filed.

The priority date of the instant claims is therefore the filing date of Applicant's amendment to the claims, 09/02/2010.

***Claim Rejections - 35 USC § 103***

9. The rejection of claims 1-13 and 20 under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass), is withdrawn in response to Applicant's amendment.

10. The rejection of claims 1-13 and 18-20 under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass) as applied to claims 1-13 and 20 above, and further in view of Saito, et al. (2003, Adv. Drug Del. Rev., v.55:199-215, item 63 on 11/08/2007 IDS) (Saito), is withdrawn in response to Applicant's amendment.

11. The rejection of claims 1-13, 20, and 21 under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS) (Cammass) as applied to claims 1-13 and 20 above, further in view of Summerton, et al. (1997, Nuc. Acid Drug Dev., v.7:187-95, item 38 on 11/08/2007 IDS) (Summerton), is withdrawn in response to Applicant's amendment.

12. The rejection of claims 1-13, and 20-23 under 35 U.S.C. 103(a) as being unpatentable over LaFleur, et al. (10/29/2002, U.S. Patent 6,472,512) and Cammas, et al. (1999, Internat. J. Biol. Macromol., v.25:273-82, item 55 on 11/08/2007 IDS)

Art Unit: 1633

(Cammass) as applied to claims 1-13 and 20 above, further in view of Khazenzon, et al. (2003, Mol. Cancer Ther., v.2:985-94, item 47 on 11/08/2007 IDS) (Khazenzon), is withdrawn in response to Applicant's amendment.

***Claim Rejections - 35 USC § 102***

13. The rejection of claims 1, and 18-20 under 35 U.S.C. 102(a) as being anticipated by Bulmus et al. is withdrawn in response to Applicant's amendment to the claims.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-2, 6-13, and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (IDS: 06/09/10).

16. Lee et al. discloses a multifunctional drug delivery construct consisting of modules attached to the pending carboxyl groups of polymalic acid. The polymer is a natural product of *Physarum polycephalum*. The modules are (1) Morpholino antisense oligonucleotides attached to the scaffold by disulfide, which is cleaved in the cytoplasm to release the free drug, (2) an antibody against transferrin receptor for cancer cell targeting and receptor-mediated endocytosis, (3) short chain PEG-coupled L-leucine and directly coupled L-valine, both by amide bonds, to provide pH-dependent lipophilicity to disrupt endosomal membranes, (4) long chain PEG for protection, (5) fluorescent reporters (fluorescein or Cy5) to detect the construct in tissue/cell.

***Claim Objections***

17. Claims 3-5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

19. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 06/09/10 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1633

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/  
Primary Examiner, Art Unit 1633